IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and INTERMUNE, INC., Plaintiffs, v. AUROBINDO PHARMA LIMITED, et al., Defendants.	C.A. No. 19-078 (RGA) CONSOLIDATED REDACTED – PUBLIC VERSION

LETTER TO THE HONORABLE RICHARD G. ANDREWS FROM STEPHEN B. BRAUERMAN OPPOSING DISQUALIFICATION OF DEFENDANTS' EXPERT, DR. VICTOR THANNICKAL

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Dear Judge Andrews,

Plaintiffs' unsupported motion to disqualify Dr. Thannickal as an expert should be denied. Disqualification is "a drastic measure which courts should hesitate to impose except when absolutely necessary." *Syngenta Seeds, Inc. v. Monsanto Co.*, No. 02-1331 (SLR), 2004 WL 2223252, at *1 (D. Del. Sept. 27, 2004) (quote omitted). Plaintiffs bear the burden of making the threshold showing that they (1) had an objectively reasonable belief of a confidential relationship with Dr. Thannickal and (2) actually disclosed confidential information to him. *See, e.g., id.; see also H. Lundbeck A/S v. Apotex Inc.*, No. 18-88 (LPS), 2020 WL 1285834, at *1 (D. Del. Mar. 18, 2020). The court must also analyze "competing policy objectives and concerns for fundamental fairness," including parties' "access to qualified expert witnesses." *Syngenta*, 2004 WL 2223252 at *2-3. Plaintiffs have not met their burden, and their motion should be denied.[1]

I. Belief in Confidential Relationship with Dr. Thannickal Not Objectively Reasonable

In their 700+ pages of exhibits, Plaintiffs cite to no agreement between Dr. Thannickal and InterMune relating to his clinical study work. Instead, they try to [redacted] to argue that they had a belief in a "confidential relationship" with Dr. Thannickal. *See* Pl. Br. at 1-2. This belief is unreasonable. [redacted] This was not a situation where a single employee was provided with information that was expected to remain secret indefinitely for the purpose of performing substantive analytical work, as in the case law Plaintiffs rely on. *See Tabaian v. Intel Corp.*, No. 3:18-cv-00326-HZ, 2018 U.S. Dist. LEXIS 163011, at *8-19 (D. Or. Sep. 22, 2018). [redacted] Given these facts, it is unreasonable for Intermune to believe a confidential relationship exists with [redacted] Dr. Thannickal.

II. No Evidence That Any Confidential Information Was Provided to Dr. Thannickal

Plaintiffs rely primarily on two examples of purportedly "confidential" information that Dr. Thannickal may have received: the protocols and investigators' brochures from clinical studies, and [redacted]. Pl. Br. at 2-3. They also speculate that he *may* have viewed [redacted]. Plaintiffs provide no information about the content of these materials and no evidence that Dr. Thannickal actually received any such materials. *Id.* This speculative and conclusory argument does not demonstrate that Dr. Thannickal *actually received* "confidential information," as required for disqualification.

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[1] If the Court grants Plaintiffs' motion, Defendants request leave to substitute a new expert for Dr. Thannickal for the purpose of ongoing claim construction briefing.

[2] References to numbered exhibits refer to the exhibits attached to Plaintiffs' letter brief.

Moreover, although Plaintiffs refer to "confidential information," they offer no evidence that any of it meets the standard for "confidentiality" under a motion to disqualify. The party seeking disqualification must "point to *specific and unambiguous disclosures* that if revealed would prejudice the party," not merely any quantum of non-public information. *CreAgri, Inc. v. Pinnaclife Inc.*, No. 5:11-06635 (LHK), 2013 WL 6700395, at *5 (N.D. Cal. Dec. 18, 2013) (quotes and citations omitted; emphasis in original). As a result, most courts considering the issue have held that "confidential information" covers "discussions related to the litigation, such as strategy, kinds of experts and their roles, and strengths and weaknesses of each side," but that "technical information as opposed to legal advice is not considered confidential" in almost all cases. *Id.*; *see also, e.g.*, *Koch Ref. Co. v. Jennifer L. Boudreau M/V*, 85 F.3d 1178, 1182 (5th Cir. 1996) ("[P]urely technical information is not confidential"); *Syngenta*, 2004 WL 2223252 at *3; Decl. ¶ 7. While technical information may occasionally be relevant if it raises legitimate concerns of prejudice—for instance, "highly sensitive clinical information that is not yet public or… not intended ultimately to be public"—Plaintiffs have made no such showing for the isolated passages of their documents that they allege to be unpublished. *Warner Chilcott Co. v Teva Pharms. USA, Inc.*, No. 08-627 (LPS), D.I. 275, at 18-20 (D. Del. Sept. 6, 2011) (Ex. 7).

Even if the information purportedly disclosed to Dr. Thannickal could have been considered "confidential" at some point in time, "[t]he test for confidential information is not whether the information was confidential at the time that it was communicated, but rather, whether its disclosure now would prejudice [the objecting party]." *CreAgri*, 2013 WL 6700395 at *7 n. 5 (subsequently published information was not "confidential"). Plaintiffs' own publications belie their argument that the clinical study protocols and manuals contain [redacted] For example, Plaintiffs repeatedly cite [redacted]—yet the PIFP-016 protocol *has* been published, in its entirety, by one of the named inventors on the patents-in-suit. *See generally* Ex. B. [redacted] study PIPF-PCLN-108, the results of which have in fact also been published. *See* Ex. C at 18-19. It is not clear what other information in [redacted] is purportedly unpublished, as extensive information regarding all of these issues is available in public documents. *See generally, e.g.*, Ex. D ([redacted]); Ex. E ([redacted]); Ex. F ([redacted]). Plaintiffs' argument that [redacted] is similarly implausible, as their parent company has a public policy of sharing data sets from its clinical studies (including "patient-level data") with outside researchers for products that have already been approved. *See* Ex. G at 4.

Plaintiffs have failed to meet their burden of showing that Dr. Thannickal received information that would qualify as "confidential information" under the case law. They have not identified a single specific piece of information that was not later published. Their speculation that the unspecified contents of documents that some of their investigators may have seen may have contained confidential information does not meet their burden of proof.

III. [redacted] Adds Nothing

[redacted]

[redacted] None of this tenuous evidence is enough to meet Plaintiffs' burden. Plaintiffs cannot fabricate a reasonable belief in a "confidential relationship" and the exchange of "confidential information" with Dr. Thannickal through [redacted].[3]

IV. Policy Weighs Against Disqualifying Dr. Thannickal

Even had Plaintiffs made a showing of a confidential relationship and disclosure of confidential information—which they have not—the public interest would weigh against disqualification. A major "policy objective[] militating against disqualification" is "ensuring that parties have access to expert witnesses who possess specialized knowledge." *Koch*, 85 F.3d at 1183 (5th Cir. 1996). Plaintiffs have not shown any prejudice from Dr. Thannickal's service as an expert and, in contrast, disqualification on this basis would prejudice Defendants.

Not only have Plaintiffs failed to show that any information Dr. Thannickal purportedly received was confidential, sensitive, or of commercial importance, but all purported examples of such information is in documents that have already been produced to Defendants in this litigation. [redacted] A Delaware court recently confronted a motion to disqualify with nearly identical facts, where an expert "enrolled subjects in four clinical studies [involving the drug at issue in the case] during which he received limited information from Plaintiffs"—presumably including clinical study protocols and/or investigator handbooks. The court denied the motion to disqualify, because the expert did not receive any privileged information in connection with the clinical trials, and "the types of technical information he did receive [were] discoverable by Defendants, thus minimizing the potential for an unfair advantage to Defendants," despite that expert's previous service as an expert on behalf of the objecting party in two prior litigations in addition to his clinical work. *H. Lundbeck*, 2020 WL 1285834 at *1.

In contrast, Defendants will be highly prejudiced if Plaintiffs can successfully disqualify an expert witness based on the bare fact of participation in a clinical trial. By Plaintiffs' logic, [redacted] doctors who served as investigators or sub-investigators in clinical trials involving pirfenidone would be ruled out as experts for Defendants. None of Plaintiffs' arguments are unique to Dr. Thannickal, and the logic expressed in their motion strongly suggests that they intend to similarly object to any other expert who received InterMune's clinical trial protocols. Plaintiffs' tactical desire to prevent Defendants from accessing any of these IPF doctors as experts is not, however, a valid basis for a motion to disqualify. Defendants request that Plaintiffs' motion be denied.

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[3] During a meet and confer, Plaintiffs threatened to disrupt Dr. Thannickal's relationship with his employer unless he agreed to withdraw as an expert. Such inappropriate behavior underscores the weakness of Plaintiffs' motion.

Respectfully,

/s/ Stephen B. Brauerman

Stephen B. Brauerman (#4952)

Attachments

cc: All Counsel of Record (via electronic mail; w/attachments)